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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,123	10/22/2003	Stephen J. Brand	24492-011	5348
30623	7590	03/21/2006	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			CORDERO GARCIA, MARCELA M	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,123	Applicant(s) BRAND ET AL.	
	Examiner Marcela M. Cordero Garcia	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-110 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-110 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

For the restriction below, please note that Examiner ascertained that based on its limitations, claim 35 should depend on claim 33 rather than on claim 32, and therefore claim 35 and dependent claims have been grouped along with claim 33 (Group I). Also please note that there is a duplicate claim 90 and that claim 95 is missing. Accordingly, the secondly presented claim 90 and claims 91-94 have been renumbered by Examiner to claims 91-95, in accordance with 37 CFR 1.75(f). Any amendments to the claims should include this correction.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 7-10, 12-14, 24-26, 33-44 and 45, 101-107 and 110 drawn to a method for treating diabetes, classified, e.g., in class 514, subclass 12.
- II. Claims 5-11, 15 and 24-26, drawn to a second method for treating diabetes, classified, e.g., in class 530, subclass 402.
- III. Claims 16-20, 49, 58-61, 63, 92-100, drawn to a composition comprising a gastrin/CCK receptor ligand and a FACGINT, classified, e.g., in class 530, subclass 326.
- IV. Claims 21-23, 24-26-27-31, 32, 45 and 91, drawn to a method for expanding and differentiating stem cells into insulin secreting cells, classified, e.g., in class 530, subclass 327.
- V. Claims 46-47, drawn to a kit, classified, e.g., in class 514, subclass 12.

- VI. Claims 48-71, drawn to a pharmaceutical composition for sustained release comprising: a gastrin receptor ligand; and an EGF receptor ligand or a FACGINT, classified, e.g., in class 514, subclass 14.
- VII. Claims 72-86, drawn to a method of reducing frequency of treating a diabetic subject, classified, e.g., in class 514, subclass 15.
- VIII. Claims 87-90, drawn to a method for expanding and differentiating stem cells into insulin secreting cells, classified, e.g., in class 514, subclass 17.
- IX. Claim 108, drawn to a method for expanding a functional β cell mass of pancreatic islet transplants in a diabetic patient, classified, e.g., in class 536, subclass 23.1.
- X. Claim 109, drawn to a method of treating human diabetes comprising transplanting a pancreatic islet preparation into a diabetic patient, classified, e.g., in class 514, subclass 16.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-II, IV and VII-X are directed to different inventions which are not connected in design, operation, or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The compositions of Groups III, V and VI are different and distinct, each from the other, because they comprise one or more structural features that are mutually

exclusive from the structural features of the compositions of the other groups. No group would render either of the other obvious, and separate searches are required for each.

Inventions III and I-II, IV, IX and X (distinct methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the instantly claimed compositions may also be used for in vitro studies of protein expression.

Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to compositions including immunosuppressive agents, sustained release formulations *with* EGF receptor ligand, a method of reducing frequency of by administering at least one component of the composition as sustained release, and a different method by use of a continuous release device, therefore they would necessitate separate searches and consideration.

The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

No matter which group is elected, a further election of species is required because this application contains claims directed to the following patentably distinct species: the many and multiple components of the composition to be used in the

instantly claimed methods. The species are independent or distinct because they encompass combinations of different and distinct compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species [i.e., elect a single and specific combination with all its components (e.g., FACGINT (and/or an EGF receptor ligand), gastrin/CCK receptor ligand and immunosuppressive agent fully identified), as necessitated by the elected Group above] for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-111 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

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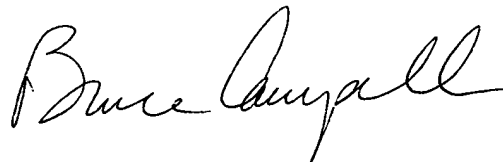
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 03/06



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